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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,437	03/26/2004	Gene A. Bornzin	A04P1029	9799

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PACESETTER, INC.
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EXAMINER	
REIDEL, JESSICA L	
ART UNIT	**PAPER NUMBER**
3766	
MAIL DATE	**DELIVERY MODE**
01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,437	BORNZIN ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15-18,20-26 and 28-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13,15-18 and 20-26* is/are rejected.

7)☒ Claim(s) *28-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on October 12, 2007. Claims 12, 14, 19 and 27 have been cancelled. Claims 1-11, 13, 15-18, 20-26 and 28-35 are pending.

Oath/Declaration

2. In view of Applicant's response filed October 12, 2007, the objections applied against the Oath/Declaration in the Office Action of June 12, 2007 have been withdrawn. The Examiner accepts the substitute Declaration filed October 12, 2007.

Specification

3. In view of Applicant's response filed October 12, 2007, the objections applied against the Specification in the Office Action of June 12, 2007 have been withdrawn.

4. The disclosure is objected to because of the following informalities: inadvertent typographical errors. At page 13, paragraph 38, line 11, the Examiner suggests changing "atrial contraction (i.e. ventricular volume after active filling)" to read, "atrial contraction (i.e. ventricular volume after passive filling)" since it was previously defined at page 6, paragraph 12 that values of ventricular volume representative of the passive filling phase are detected during intervals just prior to atrial contraction. At page 15, paragraph 42, line 9, the Examiner suggests changing "representative of ESV" to read, "representative of EDV" instead since at lines 1-8 of that same paragraph on page 15, Applicant describes that it is left ventricular EDV that is substantially at its maximum. As to the last line of paragraph 79 at page 35, the Examiner suggests changing "neither the atria now the ventricles" to read, "neither the atria nor the

ventricles" in order to eliminate a typographical and/or grammatical error. Appropriate correction is required.

Claim Objections

5. In view of Applicant's response filed October 12, 2007, the objections applied against the claims in the Office Action of June 12, 2007 have been withdrawn.

6. Claims 1, 11, 17, 20, 21, 28 and 32 are objected to because of the following informalities: inadvertent typographical errors rendering the language indefinite and/or lacking proper antecedent basis. As to Claim 1, line 11, the Examiner suggests changing "identifying a baseline point within a cardiac cycle" to read, "identifying a baseline point in time within a cardiac cycle" instead in order to provide proper antecedent basis for all future references to the baseline point within Claim 11 and the dependent claims and to provide consistent terminology throughout. Similar changes should also be applied to line 5 of Claim 11, lines 11 and 17 of Claim 17, line 2 of Claim 20, line 2 of Claim 21, line 8 of Claim 28 and line 7 of Claim 32. Also, the Examiner suggests changing lines 11-16 of Claim 1 to read, "identifying a baseline point in time within each of a plurality of cardiac cycles for detecting the values representative of passive filling volume; detecting a signal representative of an impedance between the two ventricular electrodes at each baseline point in time; and determining a baseline passive filling volume value based on the impedance signals detected at each baseline point in time; and further comprising" since Claim 11 previously defines that "values" are detected. Similar changes should also be applied to Claims 17, 28 and 32. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-11, 13 and 20-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. As to Claim 1, although the Examiner is able to find support within the disclosure for identifying a baseline point in time within each of a plurality of cardiac cycles for detecting the values representative of passive filling volume, the Examiner is unable to find support, throughout Applicant's disclosure, that values representative of ventricular end-diastolic volume (EDV) are detected by detecting values representative of passive filling volume. It is to the Examiner's best understanding that values representative of ventricular EDV are detected during a pre-ejection interval *or* during the delivery of a ventricular pacing pulse and that those values represent the sum of both passive and active filling. The Examiner also understands that active filling may be determined by additionally detecting values representative of passive filling volumes during intervals just prior to atrial contraction within each cardiac cycle and subsequently subtracting passive filling volume from EDV (see, for example, page 6, paragraph 12 of Applicant's originally filed disclosure).

10. Specifically, as to Claim 2, although the Examiner is able to find support within the disclosure for identifying a baseline point in time within each of a plurality of cardiac cycles for detecting the values representative of passive filling volume, the Examiner is unable to find

support, throughout Applicant's disclosure, that such a baseline point in time occurs during a pre-ejection interval. It is to the Examiner's best understanding that a value of ventricular volume representative of the passive filling phase is detected during an interval just prior to an atrial contraction, as discussed at page 6, paragraph 12 of the disclosure, and that a value of ventricular volume representative of the end-diastolic volume (EDV) (i.e. the sum of both active and passive filling) is detected within a window 10-50 msecs following a ventricular depolarization, i.e. within the pre-ejection interval (see, for example, Figs. 3 and 10 and pages 6-7, paragraphs 12-14 of Applicant's originally filed disclosure). Furthermore, at pages 25-26, paragraph 62 of the originally filed disclosure, Applicant specifies that the baseline point "is preferably during an interval just prior to an atrial contraction *or* during the pre-ejection interval *or* is instead contemporaneous with delivery of a V-pulse" (emphasis added). The Examiner is unable to find, throughout the specification, support for an embodiment of heart failure evaluation and tracking that identifies baseline points during an interval just prior to an atrial contraction *and* during a pre-ejection interval *and* during delivery of a ventricular pacing pulse (emphasis added).

11. As to Claims 4, 21 and 22, although the Examiner is able to find support within the disclosure for identifying a baseline point in time within each of a plurality of cardiac cycles for detecting the values representative of passive filling volume, the Examiner is unable to find support, throughout Applicant's disclosure, that such a baseline point in time occurs during delivery of a ventricular pacing pulse. It is to the Examiner's best understanding that values of EDV represents the sum of both the active and passive filling volumes and such values may be measured during a pre-ejection interval subsequent to a ventricular depolarization or during

delivery of a ventricular pacing pulse. It is also to the Examiner's best understanding that a baseline point may be identified during an interval prior to an atrial contraction for determining passive filling volume and another baseline point may be identified during a pre-ejection interval subsequent to a ventricular depolarization or during delivery of a ventricular pacing pulse for determining the EDV such that the active filling volume contribution of the atrium may be determined by taking the difference between the EDV and the passive filling volume (see, for example, page 6, paragraph 12 of Applicant's disclosure).

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

13. Claims 1-11, 13 and 20-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 1-11, 13 and 20-26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: acquiring, detecting, or obtaining "diagnostic information". Specifically, the last lines of Claim 1 define that the method includes "storing diagnostic information indicative of heart failure", but nowhere prior does Claim 1 relate either the detected values representative of EDV or the detected values representative of passive filling volume to the "diagnostic information". The Examiner suggests changing the last line of Claim 1 to read, "storing the values representative of ventricular EDV within the implantable medical device" instead as is discussed at pages 19 and 29 of Applicant's originally filed disclosure in order to clearly point out and distinctly claim the subject matter

which Applicant regards as the invention and to eliminate the 35 U.S.C. 101 rejection(s) set forth below.

Claim Rejections - 35 USC § 101

14. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claims 1-11, 13, 15-18 and 20-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, Applicant's claims are directed to a judicial exception of 35 U.S.C. 101. The method claims of the present application relate to abstract ideas, rather than practical applications of those ideas. Specifically, the claims do not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result. See MPEP § 706.03(a). To overcome the rejection, in specific reference to Claims 1 and 17, the Examiner recommends adding a tangible, useful and concrete method step wherein the method "employs" the "detecting" by "performing an action" or "completing a method step" using a device/system of some sort. For example, incorporating a limitation into Claims 1 and 17 that requires a step of "delivering therapy in response to a detection of heart failure" would overcome the 35 U.S.C. 101 rejections against Claims 1 and 17 because the modifications would require the methods to use the detection of heart failure to produce a tangible result (i.e. administration of therapy). To overcome the rejections against Claim 6, the Examiner recommends adding a tangible, useful and concrete method step wherein the method "employs" the "evaluating" by "performing an action" or "completing a method step" using a device/system of some sort.

For example, incorporating the limitations of Claim 24 and any intervening claims into Claim 6 would overcome the 35 U.S.C. 101 rejections against Claims 6 and 7 because the modification would require the method to use evaluation of the severity of heart failure to produce a tangible result (i.e. adjustment of therapy).

Allowable Subject Matter

16. Claims 28-35 would be allowable if rewritten or amended to overcome the objection(s), set forth in this Office Action.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Chirife (U.S. 5,154,171) discloses a rate adaptive pacemaker controlled by ejection fraction where impedance measurements taken at the time of occurrence of a natural R-wave or of a paced beat in order to calculate EDV.

Judy (U.S. 2005/0203429) discloses a device and method for non-invasively determining left ventricular end-diastolic volume (LVEDV) using measurements of impedance taken at both the beginning of a pre-ejection interval and at the end of a pre-ejection interval where the pre-ejection interval is determined beat-by-beat to trigger the impedance measurements beat-by-beat.

Park et al. (U.S. 5,800,467) teaches the use of cardio-synchronous impedance measuring to provide an indication as to the contractility of the heart where impedance is measured during rapid ejection (i.e. mechanical contraction or depolarization of the ventricles).

Corbucci (U.S. 2002/0151938) and Chirife (U.S. 6,119,040) both disclose tracking of pre-ejection interval duration in order to evaluate myocardial performance and/or regulate rate-adaptive pacing.

Weinberg (U.S. 2004/0002741) teaches that the progression or regression of left ventricular dysfunction (LVD) may be automatically evaluated by tracking changes in the resting sinus rate of the patient.

Wang et al. (U.S. 2005/0080460) disclose the use of cardiac-gated impedance measurements where intra-thoracic impedance is measured during either the pre-ejection period or just prior to a scheduled pacing pulse in order to measure the intra-thoracic impedance at a point in time when the heart volume is not rapidly changing to monitor pulmonary congestion/edema or dryness accurately and without lead impedance or tissue impedance changes influencing the measurements.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
January 7, 2008

Carl H. Layno
CARL LAYNO
PRIMARY EXAMINER